DEPARTMENT OF HEALTH AND HUMAN SERVICE

HFI-35

Public Health Service

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Refer to: CFN 1124036

Food and Drug Administration
Baltimore District Office
Central Region
900 Madison Avenue
Baltimore, MD 21201-2199
Telephone: (410) 962-3396
FAX: (410) 962-2307

August 26, 1999

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Larry Stanley, R.T.
Director of Radiology
Fairmont General Hospital, Inc.
1325 Locust Avenue
Fairmont, West Virginia 26554

RE: Inspection ID #112270005

Dear Mr. Stanley:

A representative from the Food and Drug Administration (FDA) inspected your facility on July 15, 1999. This inspection revealed a serious regulatory problem involving mammography performed at your facility.

Under a United States Federal law, the Mammography Quality Standards Act of 1992, your facility must meet specific requirements for mammography. These requirements help protect the health of the public by assuring that a facility can perform quality mammography. The inspection revealed the following Level 1 finding at your facility:

> **The medical physicist, [redacted], did not have a Bachelors degree in a physical science, with 10 semester hours in physics.**

The specific problem noted above appeared on your MQSA Facility Inspection Report, issued at the close of the inspection.

Because this condition may be symptomatic of serious underlying problems that could compromise the quality of mammography performed at your facility, it represents a serious violation of the law which may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to: placing your facility under a Directed Plan of Correction; charging your facility for the cost of on-site monitoring; assessing civil money penalties up to $10,000 for each failure to substantially comply with, or each day of failure to substantially comply with, the Standards; suspension or revocation of your facility's FDA certificate; or obtaining a court injunction against further mammography.

It is necessary for you to act on this matter immediately. Please explain to this office in writing within fifteen (15) working days from the date you receive this letter:

- the specific steps you have taken to correct all of the violations noted in this letter;
- each step your facility is taking to prevent the recurrence of similar violations;
- equipment settings (including technique factors), raw test data, and calculated final results, where appropriate; and
- sample records that demonstrate proper record keeping procedures, if the findings relate to quality control or other records. (Note: Patient names or identification should be deleted from any copies submitted.)*

(*This is not applicable for letters which also address patient notification.)

Please submit your response to:

Food and Drug Administration
Richmond Resident Post
10710 Midlothian Turnpike
Suite 424
Richmond, Virginia 23235
Attn: Scott J. MacIntire, Compliance Officer

Finally, you should understand that there are many FDA requirements pertaining to mammography. This letter pertains only to findings of your inspection and does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for mammography facilities by contacting the Mammography Quality Assurance Program, Food and Drug Administration, P.O. Box 6057, Columbia, MD 21045-6057 (1-800-838-7715), or through the Internet at http://www.fda.gov.

If you have specific questions about mammography facility requirements or about the content of this letter, please feel free to contact Elizabeth A. Laudig at (410) 962-3591, extension 159.

Sincerely yours,

James M. Strachan
Acting District Director